

## REMARKS

### Rejections Under 35 U.S.C. §112, second paragraph

The Examiner stated that original claims 1 and 22 are unclear because they include optional steps. The Examiner suggested that the optional steps be introduced as dependent claims. Claim 22 has been cancelled. Claim 1 has been amended to remove the dependent steps. The dependent steps in original claim 1 are now in newly added dependent claims 33-35.

The Examiner stated that the phrase "mechanically expressing" in original claim 1 is unclear. Claim 1 has been amended to replace the step of "mechanically expressing" with a step of "applying pressure" to the tissue "to remove undesirable component from the tissue". Support for this amendment is found in the specification on page4, lines 29-30.

The Examiner stated that original claims 6 and 26 are unclear with respect to the meaning and scope of the phrase "combining said biopolymer scaffold material with scaffolds made from naturally occurring, man-made or self-degrading polymers". Claim 26 has been cancelled. Claim 6 has been amended to delete the phrase objected to by the Examiner.

In claims original 5, 6, 25 and 26, the Examiner has requested that the word "a" be inserted before the word "lesion". Claim 5 has been amended as suggested by the Examiner. Claim 6 has been amended to delete the word "lesion". Claims 25 and 26 have been cancelled.

In original claims 6, 26, and 30, the Examiner suggested that the word "delivery" be inserted after "complex". Claim 6 has been amended to delete the word "complex". Claims 26 and 30 have been cancelled.

The Examiner stated that original claims 6 and 26 are unclear in requiring that factors extracted from the tissue be added where the claim did not require that such factors be removed in the first instance. The Examiner also stated that the sodium hydroxide treatment step is unclear. Claims 6 and 26 have been cancelled. New claim 35 depends from claim 1 and requires the extraction of growth and differentiation factors. New claim 36 depends from claim 35 and specifies combining the biopolymer scaffold material with "growth and differentiation factors that have been extracted from said tissue and then treated with sodium hydroxide having a concentration consistent with the retention of biological activity".

The Examiner rejected claims 7-19 as unclear for not including method steps for not clearly relating back to the lesion or damaged tissue of claim 5. Each of claims 7-19 have been amended to depend from claim 1 and to include a method step.

The Examiner rejected claims 21, 24, 26, 27, 28, 30 and 31 for various reasons. Applicants have cancelled claims 21, 24, 26, 27, 28, 30 and 31.

#### Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1-31 as allegedly unpatentable over Brendel et al. (U.S. Patent 4,801,299) in view of Bell et al. (U.S. Patent 6,179,872). According to the Examiner, Brendel et al. discloses producing an extracellular matrix "by treating tissue to remove cellular membranes, nucleic acids, lipids and cytoplasmic components by treating tissue with detergents, washing, treating ... to sterilize, and lyophilizing". Also according to the Examiner, Bell et al. teaches preparing tissue for use in a biopolymer matt "by grinding, washing and sieving to remove cytoplasmic and nuclear components". The Examiner concludes that it would have been "obvious to use grinding of tissue in removing cytoplasmic components in the method of Brendel et al. for producing an extracellular matrix as suggested by Bell et al., using grinding for removing cytoplasmic components to produce an extracellular matrix". According to the Examiner, "grinding is mechanically expressing".

First, Applicants do not conceded that Bell et al. can properly be cited against the present claims in a rejection under 35 U.S.C. §103 as prior art under 35 U.S.C. §102(e) since the present application and Bell et al. were under common obligation of assignment to the same entity, Tissue Engineering, Inc.

Second, has been amended replace the phrase "mechanically expressing" with a step of "applying pressure" to the tissue "to remove undesirable components". This is not equivalent to grinding. Thus, the cited references, no matter how combined cannot render the present claims obvious.

Applicant : Jianwu Dai et al.  
Serial No. : 09/996,640  
Filed : November 28, 2001  
Page : 9 of 9

Attorney's Docket No.: 13343-023001

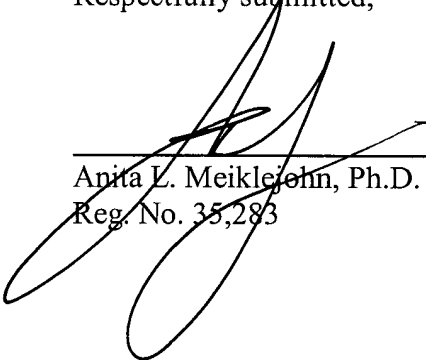
Double Patenting

The Examiner provisionally rejected claims 1-31 under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 22-46 of co-pending application U.S. Serial. No. 09/871,518. Upon indication that there are allowable claims in the present application, Applicants will file a suitable terminal disclaimer in this application or take other appropriate action to overcome this provisional rejection.

Enclosed is a Petition for Extension of Time with the appropriate fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 22 Sept 2003

  
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